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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,408	05/09/2001	Carlos Schuler	015225-005910US	5388

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EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3743	17

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,408	SCHULER ET AL.	
	Examiner	Art Unit	
	Nihir Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 25th, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-22,24-32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11, 15- 22, 24, 25, and 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodman et al. US Patent No. 5,404,871. Referring to claim 1, Goodman discloses a delivery of aerosol medications for inspiration that does provide a disposable container 3200 (see figure 2A) adapted to contain a drug formulation; an aerosol generator 3130 (see figure 2A) for aerosolizing the drug formulation in response to manual actuation; and an electronic prevention device which prevents aerosolization of the drug formulation when in an inactive state and which permits aerosolization of the drug formulation when electric current is supplied to place the prevention device in an activated state (see column 19 lines 64-68 and column 20 lines 1-6).

Referring to claim 2, Goodman discloses an apparatus wherein the prevention device comprises an electronic lockout device having a lockout element that is positioned in a dose preventing position when in the inactive state, and is movable to a dosing permitting position when electric current is supplied to place the lockout device in the activated state. (see column 19 lines 64-68 and column 20 lines 1-6).

Referring to claim 3, Goodman discloses an apparatus wherein the lockout device further comprises circuitry for applying electrical current to move the lockout element to the dose

permitting position when the lockout device is in the activated state (see column 19 lines 64-68 and column 20 lines 1-6).

Referring to claim 4, Goodman discloses an apparatus wherein the lockout device further comprises a controller having an associated memory for storing a dosing condition, and wherein the controller is configured to send a signal to place the lockout device in the activated state only after the dosing condition has been satisfied (see column 22 lines 55-68).

Referring to claim 5, Goodman discloses an apparatus wherein the container comprises a canister 3200 (see figure 2A), and wherein the aerosol generator comprises a metering valve and an actuator operably coupled to the canister (see figure 2A).

Referring to claim 6, Goodman discloses an apparatus further comprises a housing wherein the canister 3200 is reciprocally held within at least a portion of the housing between a home position and a dosing position where the actuator is engaged to open the metering valve and to permit the escape of a metered amount of the drug formulation from the canister (the term "one or more doses" in broad sense is similar to metered amount).

Referring to claim 7, Goodman discloses an apparatus wherein the lockout element is positioned to prevent engagement of the actuator when in the dose prevention position to thereby prevent opening of the metering valve (see figure 2A).

Referring to claim 8, Goodman discloses an apparatus wherein the lockout element has a distal end that is engageable with the canister to prevent substantial displacement of the canister into the housing when in the lockout device is in the dose preventing device (see figures 2B and 3).

Referring to claim 9, Goodman discloses an apparatus wherein upon placement of the preventing device into the activated state, the distal end of the lockout element is retracted to permit displacement of the canister into the housing and to permit engagement of the actuator to open the metering valve (see figures 2B and 3).

Referring to claim 11, Goodman discloses an apparatus that further comprise a high pressure gas source to assist in aerosolizing the drug formulation when the preventing device is in the activated state (see column 19 lines 50-60).

Referring to claim 15, Goodman discloses an apparatus further comprising a nozzle 3160 operably coupled to the canister and wherein the housing further includes a mouthpiece 3110 (see figure 2A) disposed to receive the drug formulation from the nozzle (see figure 2A).

Referring to claim 16, Goodman discloses an apparatus wherein the mouthpiece 3110 has a first end and a second end, and wherein the nozzle is positionable within an opening adjacent the first end of the mouthpiece to permit the aerosolized drug formulation to be delivered to a patient upon inhalation through the second end of the mouthpiece (see figure 2A).

Referring to claim 17, Goodman disclose a delivery of aerosol medications for inspiration that provides a container 3200 (see figure 2A) having an amount of drug formulation that is aerosolized in response to manual actuation (see column 19 lines 15-30); preventing the aerosolization of the drug formulation with an electronic lockout device by maintaining the lockout device in an inactive state (see column 19 lines 64-68); and supplying electrical current to the lockout device to place the lockout device in an active state, thereby permitting the aerosolization of the drug formulation (see column 20 lines 1-6).

Referring to claim 18, Goodman discloses an apparatus wherein the electronic lockout device comprises a lockout element that is positioned in a dose preventing position when in the inactive state, and further comprising moving the lockout element to a dosing permitting position when electric current is supplied to place the lockout device in the activated state (see column 19 lines 64-68 and column 20 lines 1-6).

Referring to claim 19, Goodman discloses an apparatus wherein the container comprises a canister 3200 (seee figure 2A) having a metering valve and an actuator, wherein the canister is reciprocatably held within a housing between a home position and a dosing position, and further comprising depressing the canister into the housing to the dosing position to engage the actuator and to release a metered amount of the drug formulation when in the lockout device is in the active state (see figures 2A, 2B, and 3).

Referring to claim 20, Goodman discloses an apparatus that further comprises preventing engagement of the actuator when the lockout element is in the dose preventing position (see figures 2A, 2B, and 3).

Referring to claim 21, Goodman discloses an apparatus that further comprises engaging the canister with the lockout element to prevent movement of the canister to the dispensing position when the lockout element is in the dose preventing position (see column 19 lines 64-68 and column 20 lines 1-6).

Referring to claim 22, Goodman discloses an apparatus that further comprises a disengaging the lockout device element from the canister to permit movement of the canister to the dispensing position upon supply of the electrical current (see figure 2A, 2B, and 3; column 19 lines 64-68 and column 20 lines 1-6).

Referring to claim 24, Goodman discloses an apparatus that further comprises stopping the supply current of the electric current to the lockout device after the drug formulation has been aerosolized (see column 19 lines 64-68 and column 20 lines 1-6).

Referring to claim 25, Goodman discloses an apparatus that further comprises supplying electric current to the lockout device to permit another dosing only after a certain dosing condition has been satisfied (see column 19 lines 64-68, column 20 lines 1-6, and column 22 lines 55-68).

Referring to claim 28, Goodman discloses a delivery of aerosol medications for inspiration that comprises a housing having a mouthpiece 3110 (see figure 2A); a canister 3200 (see figure 2A) that is movable within the housing when manually depressed into the housing, the canister having a metering valve that is operable to release a metered amount of drug formulation from the canister; and a control system comprising a locking mechanism that may be in an active or inactive state, wherein the control system controls the opening of the valve such that the valve is only opened when a force is manually applied to depress the canister into the housing and when a dosing condition has been satisfied at which time the locking mechanism in the active state (see figures 2A, 2B, and 3).

Referring to claim 29, Goodman discloses an apparatus wherein the control system comprises a controller, wherein the controller is configured to send a signal to the locking mechanism to activate the locking mechanism to permit opening of the valve once the dosing condition has been satisfied (see column 19 lines 64-68, column 20 lines 1-6, and column 22 lines 55-68).

Referring to claim 30, Goodman discloses an apparatus wherein the dosing condition is the passage of certain amount of time between dosings, and further comprising an electronic clock coupled to the controller to measure the passage of time between dosings (see column 22 lines 50-68).

Referring to claim 31, Goodman discloses an apparatus wherein the locking mechanism is normally in a dose preventing position and is movable to a dosing position when electrical current is supplied to the locking mechanism to permit opening of the valve when the canister is depressed (see figures 2A, 2B, and 3).

Referring to claim 32, Goodman discloses an apparatus wherein the locking mechanism includes a locking element that engages the canister to prevent depression of the canister into the housing when in the dose preventing position (see figures 2A, 2B, and 3).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-14, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman US Patent No. 5,404,871 in view of Ritson Patent No. WO 94/16759. Referring to claims 12, Goodman discloses the applicant's invention as claimed with the exception of providing a dose counter disposed to count the number of doses of the drug formulation dispensed from the container.

Ritson discloses an automatic aerosol medication delivery system and methods that does provide a dose counter disposed to count the number of doses of the drug formulation dispensed from the container (see page 37 lines 15-27). Therefore it would be obvious to modify Goodman's invention by providing a dose counter disposed to count the number of doses of the drug formulation dispensed from the container in order to notify the amount of medication available to the patent.

Referring to claims 13 and 26, Goodman discloses the applicant's invention as claimed with the exception of providing a dose counter that comprises a dose counting circuit positioned to sense when the container has been reciprocated within the housing.

Ritson discloses an automatic aerosol medication delivery system and methods that does provide a dose counter that comprises a dose counting circuit positioned to sense when the container has been reciprocated within the housing (see page 37 lines 15-27). Therefore it would be obvious to modify Goodman's invention by providing a dose counter that comprises a dose counting circuit positioned to sense when the container has been reciprocated within the housing in order to have accurate count.

Referring to claims 14 and 27, Goodman discloses the applicant's invention as claimed with the exception of providing a dose counter that further comprises a display for indicating if the container contains an amount of drug formulation.

Ritson discloses an automatic aerosol medication delivery system and methods that does provide a dose counter that further comprises a display for indicating if the container contains an amount of drug formulation (see page 37 lines 15-27). Therefore it would be obvious to modify Goodman's invention by providing a dose counter that further comprises a display for indicating

if the container contains an amount of drug formulation in order to notify the patient that it may be time to refill.

Claims 34, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. US Patent No. 5,404,871 in view of Von Wielligh US Patent No. 6,024,097.

Referring to claims 34 and 35, Goodman discloses the applicant's as claimed with the exception providing an amount of a nicotine formulation and aerosolizing it.

Von Wielligh discloses a product for assisting a smoker in giving up the habit that does provide an amount of a nicotine formulation and aerosolizing it. Therefore it would be obvious to modify Goodman's invention by providing an amount of a nicotine formulation and aerosolizing it in order to assist the patient in giving up smoking.

Referring to claim 36, Goodman discloses the applicant's invention as claimed with the exception of providing a container that contains a drug formulation that contains nicotine.

Von Wielligh discloses a product for assisting a smoker in giving up the habit that does provide a container 10, 12, 14, and 16 that contains a drug formulation that contains nicotine. Therefore it would be obvious to modify Goodman's invention by providing a container that contains a drug formulation that contains nicotine in order to assist the patient in giving up smoking.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP
March 8th, 2004

Henry Bennett
Supervisory Patent Examiner
Group 3700